

REMARKS

Claims 1, 3-5, 8-9, 11, 14 and 21 are pending. The pending claims relate to a substance delivery device particularly useful for the delivery of drugs for use in animal body cavities, such as a vagina.

Rejections under 35 U.S.C. §102(b)

The Examiner rejects Claims 1, 4-5 and 8 under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 4,369,783 to Hiller *et al.* ("Hiller"). Applicants respectfully traverse the rejection. MPEP 2131 provides: "To anticipate a claim, the reference must teach each and every element of the claim." Applicants respectfully assert that Hiller fails to anticipate the rejected claims because it fails to teach at least one element of the claims.

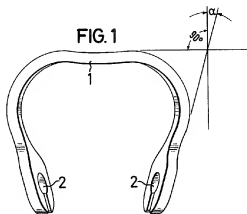
Claim 1 recites "a support frame having at least two resilient arms which retain the inserted internal substance delivery device within the body cavity and against a mucosal membrane of the body cavity, ... wherein each distal end of the at least two resilient arms and pods attached to the arms are biased outward from a central section of the support frame." Applicants respectfully assert that Hiller fails to teach a device with arms biased outward from a central section, which retain the device against a mucosal membrane of a body cavity.

Hiller discloses a bow-shaped nose-clip ("nose-clip") for treatment of cattle with the receiving ends (also referred to as "terminal means") for active ingredients in the form of "depot bodies." *See* Hiller, abstract, Figure 1 (reproduced below), column 1, 60-65. The terminal parts of the nose-clip are inclined towards each other and "substantially adapted to the anatomic conditions at ... the mucosa of the nasal septum in the nasal vestibule," where the depot bodies "must form defined angles with the nasal mucosa." *See* Hiller, column 1, lines 29-31, lines 35-38.

The Examiner's position, as expressed on top of page 3 of the Office Action, is that the nose-clip disclosed in Hiller includes two resilient arms and pods attached to the arms

that are biased outward from a central section, which retain the inserted internal substance delivery device against a mucosal membrane of the body cavity. On page 7 of the Office Action, the Examiner asserts that the arms of the nose-clip in Hiller are “fully capable of being biased in two directions,” and further suggests that it is possible to use the nose-clip by squishing the arms, thus decreasing its width, inserting the nose-clip into the body cavity, and then releasing the arms, which then would be “biased outwards attempting to return to the standard state.”

Applicants respectively disagree with the Examiner’s interpretation of Hiller. Hiller teaches in column 1, lines 25-27 and lines 40-42 that the terminal parts of the nose-clip are inclined towards each other. This angle is also illustrated in Figure 1 of Hiller, reproduced below. Furthermore, in column 1, line 65, through column 2, line 3, Hiller discloses that the terminal means are inclined towards one another at an angle that is greater than 0°, most desirably between 8° and 28°. The configuration of the nose-clip allows for optimal force and relaxation for its insertion in the nasal vestibule. See Hiller, column 2, lines 6-34. Furthermore, Hiller states that the terminal means or depot bodies are turned to face one another. See Hiller, column 2, lines 1-5.



Hiller, Figure 1

Applicants respectfully assert that, even if the nose-clip disclosed in Hiller were to be placed into a body cavity, such as a vagina, as the Examiner proposes, the nose-clip would not be kept in place by the arms “biased outwards attempting to return to the standard state.” The nose-clip in Hiller is a compression, or clamp, mechanism. Its arms are biased inward and its resting position is with inward pressure, so that the nose-clip can clamp onto the nasal septum and cause the inwardly facing drug delivery portion of the device to contact the mucous membrane on each side of the nasal septum. In other words, since the arms are biased inward, the nose-clip must be expanded outward in order for it to be placed onto the nasal septum. The nose-clip resists outward deflection (or distortion). Once the expanded nose-clip is placed over the nasal septum, and the expansion force is released, the nose-clip returns to its resting, inward-biased compressed position. The nose-clip thus fixes onto the nasal septum with the inwardly turned drug-delivery parts (terminal means) in contact with the septal mucous membranes.

Applicants further assert that, if one attempted to compress or “squish” the nose-clip and place it into an undivided body cavity, such as a vagina, in the hope of retaining it there, the wall pressure of the cavity would actually further decrease the distance between the terminal means of the nose-clip. Since the arms of the nose-clip are already biased inwards for optimal clamping onto the nasal septum, further inward pressure from the cavity walls would “squish” the device inward. Rather than pressing outwards onto the vaginal cavity walls and staying in place, the nose clip would fall out of the cavity. Accordingly, the arms of the nose-clip could not retain the nose-clip within the body cavity, as recited in the pending claims. Furthermore, the inwardly turned terminal means in the nasal clip (positioned for contact with the nasal septum located between them) would not contact the surrounding cavity walls, as recited in the claims, and would not deliver the drug to the mucosal membrane.

In contrast, the outward bias of the arms of the claimed device maintains its position within the body cavity. The claimed device is compressed inward for insertion into the body cavity, and the arms attempt to return to their outward-biased resting position, thus maintaining the device in place. The pods capable of releasing a drug are also biased outwards,

thus enabling them to contact the surrounding mucosal membrane of the walls of the body cavity upon insertion of the device.

Due to at least the foregoing reasons, Applicants respectfully submit that Hiller *et al.*, fails to anticipate the pending claims. Applicants request withdrawal of the rejection under 35 U.S.C. §102(b).

Rejections based on 35 U.S.C. §103(a)

Hiller

The Examiner rejects Claim 11 under 35 U.S.C. §103(a) as obvious over Hiller, asserting that Hiller discloses Applicants' invention substantially as claimed, except for expressly disclosing the support frame made of nylon. Applicants respectfully traverse the rejection.

MPEP 2142 states: "To reach a proper determination under 35 U.S.C. §103, the examiner must step backward in time and into the shoes worn by the hypothetical 'person of ordinary skill in the art' when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention 'as a whole' would have been obvious at that time to that person." To reject a claim as obvious, the Examiner, first, must resolve the *Graham* factual inquiries, namely, (a) determining the scope and content of the prior art, (b) ascertaining the differences between the claimed invention and the prior art, and (c) resolving the level of ordinary skill in the pertinent art. See MPEP 2141(II) citing *Graham v. John Deere Co.*, 383 U.S. 1 (1966).

Applicants discussed in the previous section the disclosure of Hiller and the differences between the claims and the disclosure. In summary, Hiller discloses a nose-clip adapted for clamping onto a nasal septum and delivering the drug to the septum, and fails to teach or suggest the device configuration invented by Applicants and recited in the pending claims. Furthermore, if the nose-clip disclosed in Hiller were inserted into a body cavity, as

proposed by the Examiner, its arms would fail to retain the device in the cavity, and its terminal means would fail to contact the surrounding mucosal membrane, located on the walls of the body cavity, to deliver the drug. Applicants respectfully assert that Hiller, by disclosing that the terminal means of the nose-clip are inclined towards one another at an angle that is greater than 0°, most desirably between 8° and 28°, and by teaching that the configuration of the nose-clip allows for optimal force and relaxation for its insertion in the nasal vestibule, teaches away from Applicants' claimed device with two resilient arms biased outwards for retention in a body cavity, such as vagina. Accordingly, Applicants disagree with the Examiner's position that Hiller discloses Applicants' invention substantially as claimed, and assert that modifying the device in Hiller with a nylon support frame, as proposed by the Examiner, would not result in the device recited in Claim 11.

Applicants assert that, at least due to the differences discussed above, between Applicants' claimed device and the nose-clip disclosed in Hiller, Claim 11 would not have been obvious to one of ordinary skill in the art in the field of the present application at its priority date. Applicants therefore assert that Hiller fails to render obvious Claim 11 and respectfully request withdrawal of the rejection under 35 U.S.C. §103(a).

Hiller in view of Anderson

The Examiner rejects Claims 3, 9, 14 and 21 as under 35 U.S.C. §103(a) as obvious over Hiller in view of U.S. Patent No. 5,816,248 to Anderson *et al.* ("Anderson"). The Examiner asserts that Hiller discloses Applicants' invention substantially as claimed, and that modifying the disclosure of Hiller with an intravaginal release device, a wish-bone support frame or a locator, would result in the devices recited in the rejected claims. Applicants respectfully traverse the rejection.

Applicants discuss above the disclosure of Hiller and the differences between the claims and the Hiller disclosure. Anderson discloses a vaginal insert for delivering an agent to urogenital tract of a patient. *See* Anderson, Abstract. The vaginal insert disclosed in Anderson

comprises an agent-retaining member with a channel configured to engage the anterior vaginal wall and to deliver the agent to urogenital tract. *See* Anderson, column 2, lines 31-49, column 3, lines 51-52. Anderson fails to teach or suggest a device with outwardly biased arms and pods capable of releasing a drug to a mucosal membrane of a body cavity, as recited in the pending claims.

As discussed above, Applicants disagree with the Examiner's position that Hiller discloses the invention substantially as claimed. Anderson fails to provide any additional knowledge relevant to one of ordinary skill in the art in the area of the present application with regard to the delivery device configuration recited in the claims. Accordingly, Applicants assert that, by modifying the device in Hiller with various elements, as proposed by the Examiner on pages 4-5 of the Office Action, one of ordinary skill in the art in the area of the present application would fail to arrive at the devices recited in Claim 3, 9, 14 and 21.

Applicants therefore assert that Claims 3-9, 14 and 21 would not have been obvious to one of ordinary skill in the art in the field of the present application at its priority date at least due to the differences, discussed above, between Applicants' claimed device and the nose-clamp disclosed in Hiller, and also due to lack of any suggestion in Anderson regarding the device configuration recited in the pending claims. Applicants assert that Hiller or Anderson, separately or in combination, fail to render obvious the rejected claims and respectfully request withdrawal of the rejection under 35 U.S.C. §103(a).

CONCLUSION

In light of the amendments and the above remarks, Applicants are of the opinion that the Office Action has been completely responded to, and that the application is now in condition for allowance. Such action is respectfully requested.

No additional fees are believed due; however, the Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment, to Deposit Account No. 11-0855.

If the Examiner believes any informalities remain in the application that may be corrected by Examiner's Amendment, or there are any other issues that can be resolved by telephone interview, a telephone call to the undersigned agent at (404)815-6102 is respectfully solicited.

Respectfully submitted,

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